

Practitioner's Docket No. 2005-00165

PATENT
USSN: 10/806,072RECEIVED
CENTRAL FAX CENTER

MAY 23 2007

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Kindly withdraw claims 1-15 and 17 from consideration as drawn to a non-elected invention; cancel claims 16 and 18-21; amend claims 22-25, 30, and 37-40; and add new claims 44-48 as follows:

Listing of Claims:

1. (WITHDRAWN) A topical composition comprising:
 - a topical anesthetic;
 - a polymeric thickener selected from the group consisting of shear-thinning polysaccharide gums and shear-thinning polyacrylic acid polymers;
 - a lipophilic component that is selected from the group consisting of an aliphatic C₁ to C₈ alcohol, an aliphatic C₈ to C₃₀ ester, a liquid polyol and a mixture thereof;
 - water; and
 - a buffer system that provides a buffered pH value for said composition in the range of about 3 to about 7.4.
2. (WITHDRAWN) The composition of claim 1 further comprising a vasoactive prostaglandin selected from the group consisting of PGE₁, PGA₁, PGB₁, PGF_{1α}, 19-hydroxy-PGA₁, 19-hydroxy-PGB₁, PGE₂, PGA₂, PGB₂, 19-hydroxy-PGA₂, 19-hydroxy-PGB₂, PGE₃, PGF₃ and mixtures thereof.
3. (WITHDRAWN) The composition of claim 2 wherein the vasoactive prostaglandin is selected from the group consisting of prostaglandin E₁, prostaglandin E₂, a pharmaceutically acceptable salt thereof, a lower alkyl ester thereof and a mixture thereof.
4. (WITHDRAWN) The composition of claim 2 wherein the vasoactive prostaglandin is present in the amount of about 0.1 mg to about 0.5 mg.
5. (WITHDRAWN) The composition of claim 2 wherein the vasoactive prostaglandin is present in the amount of about 0.2 mg to about 0.3 mg.
6. (WITHDRAWN) The composition of claim 1 wherein the topical anesthetic is an aminoamide local anesthetic selected from the group consisting of lidocaine, bupivacaine, mepivacaine,

Practitioner's Docket No. 2005-00165

PATENT
USSN: 10/806,072

dibucaine, propivacaine, etidocaine, tlocainide, a pharmaceutically acceptable salt thereof and a mixture thereof.

7. (WITHDRAWN) The composition of claim 1 wherein the topical anesthetic is a local anesthetic selected from the group consisting of lidocaine, bupivacaine, dyclonine, a pharmaceutically acceptable salt thereof and a mixture thereof.
8. (WITHDRAWN) The composition of claim 1 wherein the topical anesthetic comprises about 0.01 to about 10 percent by weight based on the weight of the composition.
9. (WITHDRAWN) The composition of claim 1 wherein the polymeric thickener is a shear-thinning polyacrylic acid polymer.
10. (WITHDRAWN) The composition of claim 1 wherein the shear-thinning polysaccharide gum is a galactomannan gum.
11. (WITHDRAWN) The composition of claim 10, wherein the shear-thinning polysaccharide gum is a modified galactomannan gum.
12. (WITHDRAWN) The composition of claim 11 wherein the modified galactomannan gum is a modified guar gum.
13. (WITHDRAWN) The composition of claim 1 further comprising a penetration enhancer selected from the group consisting of an alkyl-(N-substituted amino) alkanolate, an alkyl-2-(N,N-disubstituted amino) alkanolate, an (N-substituted amino) alkanol alkanolate, an (N,N-disubstituted amino) alkanol alkanolate, a pharmaceutically acceptable salt thereof and a mixture thereof.
14. (WITHDRAWN) The composition of claim 13 wherein the penetration enhancer is dodecyl 2-(N,N-dimethylamino)-propionate or a pharmaceutically acceptable salt.
15. (WITHDRAWN) The composition of claim 1 wherein the lipophilic component comprises at least one glyceryl ester selected from the group consisting of monoglycerides, diglycerides, triglycerides, and mixtures thereof.

Practitioner's Docket No. 265-00165

PATENT
USSN: 10/806,072

16. (CANCELLED)
17. (WITHDRAWN) The composition of claim 1 wherein the composition further comprises an emulsifier selected from the group consisting of sucrose esters, polyoxyethylene sorbitan esters, long chain alcohols, and glyceryl esters.
18. (CANCELLED)
19. (CANCELLED)
20. (CANCELLED)
21. (CANCELLED)
22. (CURRENTLY AMENDED) A method of treating premature ejaculation in a patient needing such treatment comprising the steps of:
- administering orally to a patient in need of treatment of premature ejaculation an ejaculation latency prolonging amount of a semi-solid composition comprising:
 - a topical anesthetic;
 - a polymeric thickener selected from the group consisting of a shear-thinning polysaccharide gum gums and shear-thinning polyacrylic acid polymer polymers;
 - a lipophilic component that is selected from the group consisting of an aliphatic C₁ to C₈ alcohol, an aliphatic C₈ to C₃₀ ester, a liquid polyol and a mixture thereof;
 - water; and
 - a buffer system that provides a buffered pH value for said composition in the range of about 3 to about 7.4;
 - wherein administering the semi-solid composition confers prolongation of ejaculation latency to the patient, thereby treating premature ejaculation in the patient.
23. (CURRENTLY AMENDED) The method of claim 22 wherein the composition further comprises a vasoactive prostaglandin selected from the group consisting of PGE₁, PGA₁, PGB₁, PGF_{1α}, 19-hydroxy-PGA₁, 19-hydroxy-PGB₁, PGE₂, PGA₂, PGB₂, 19-hydroxy-PGA₂, 19-hydroxy-PGB₂, PGE₃, PGF₃ and a mixture mixtures thereof present in the amount of about 0.1 mg to about 0.5 mg.

Practitioner's Docket No. 26-5-00165

PATENT
USSN: 10/806,072

24. (CURRENTLY AMENDED) The method of claim 23 ~~22~~ wherein vasoactive prostaglandin is selected from the group consisting of prostaglandin E₁, prostaglandin E₂, a pharmaceutically acceptable salt thereof, a lower alkyl ester thereof and a mixture thereof.
25. (CURRENTLY AMENDED) The method of claim 23 ~~22~~ wherein the vasoactive prostaglandin is present in the amount of about 0.2 mg to about 0.3 mg.
26. (ORIGINAL) The method of claim 22 wherein the topical anesthetic is an aminoamide local anesthetic selected from the group consisting of lidocaine, bupivacaine, mepivacaine, dibucaine, propivacaine, etidocaine, tocainide, a pharmaceutically acceptable salt thereof and a mixture thereof.
27. (ORIGINAL) The method of claim 22 wherein the topical anesthetic is a local anesthetic selected from the group consisting of lidocaine, bupivacaine, dyclonine, a pharmaceutically acceptable salt thereof and a mixture thereof.
28. (ORIGINAL) The method of claim 22 wherein the topical anesthetic comprises about 0.01 to about 4 percent by weight based on the weight of the composition.
29. (ORIGINAL) The method of claim 22 wherein the polymeric thickener is a shear-thinning polyacrylic acid polymer.
30. (CURRENTLY AMENDED) The method of claim 22 wherein the polymeric thickener ~~polymer~~ is a shear-thinning polysaccharide gum.
31. (ORIGINAL) The method of claim 22 wherein the shear-thinning polysaccharide gum is a galactomannan gum.
32. (ORIGINAL) The method of claim 22, wherein the shear-thinning polysaccharide gum is a modified galactomannan gum.
33. (ORIGINAL) The method of claim 32 wherein the modified galactomannan gum is a modified guar gum.

Practitioner's Docket No. 2005-00165

PATENT
USSN: 10/806,072

34. (ORIGINAL) The method of claim 22 wherein the composition further comprises a penetration enhancer selected from the group consisting of an alkyl-(N-substituted amino) alkanoate, an alkyl-2-(N,N-disubstituted amino) alkanoate, an (N-substituted amino) alkanol alkanoate, an (N,N-disubstituted amino) alkanol alkanoate, a pharmaceutically acceptable salt thereof and a mixture thereof.
35. (ORIGINAL) The method of claim 34 wherein the penetration enhancer is dodecyl 2-(N,N-dimethylamino)-propionate or a pharmaceutically acceptable salt.
36. (ORIGINAL) The method of claim 22 wherein the lipophilic component comprises at least one aliphatic C₈ to C₃₀ ester.
37. (CURRENTLY AMENDED) The method of claim 22 wherein the composition lipophilic component comprises at least one glyceryl ester selected from the group consisting of a monoglyceride, a diglyceride, a triglyceride, and a mixture monoglycerides, diglycerides, triglycerides, and mixtures thereof.
38. (CURRENTLY AMENDED) The method of claim 37 22 wherein the composition lipophilic component comprises at least one glyceryl ester selected from the group consisting of glyceryl monooleate, triolein, trimyristin, tristearin, and a mixture mixtures thereof.
39. (CURRENTLY AMENDED) The method of claim 22 wherein the composition further comprises an emulsifier selected from the group consisting of a sucrose ester esters, a polyoxyethylene sorbitan ester esters, a long chain alcohol alcohols, and a glyceryl ester esters.
40. (CURRENTLY AMENDED) The method of claim 22 wherein the emulsifier comprises at least one glyceryl ester selected from the group consisting of glyceryl monooleate, triolein, trimyristin, tristearin, and a mixture mixtures thereof.
41. (ORIGINAL) The method of claim 22 wherein the composition further comprises up to about 5 percent mytenol, based on the total weight of the composition.
42. (ORIGINAL) The method of claim 22 wherein the composition further comprises a preservative.

Practitioner's Docket No. 2005-00165

PATENT
USSN: 10/806,072

43. (ORIGINAL) The method of claim 22 wherein the composition further comprises a fragrance.
44. (NEW) The method of claim 22 wherein the ejaculation latency time is no less than two minutes.
45. (NEW) The method of claim 22 wherein the ejaculation latency time is greater than two minutes.
46. (NEW) The method of claim 22 wherein the ejaculation latency is prolonged by at least two minutes.
47. (NEW) The method of claim 22 wherein the composition is administered about 2 to about 30 minutes before sexual intercourse.
48. (NEW) The method of claim 22 wherein the composition is administered 5 to 20 minutes before sexual intercourse.